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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LIN, JAMES	

ART UNIT	PAPER NUMBER
1792	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/631,228	PATHAK ET AL.	
	Examiner	Art Unit	
	Jimmy Lin	1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-14,16-29 and 31-37* is/are pending in the application.

4a) Of the above claim(s) *7,11,12,14 and 19-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,8-10,13,16-18,23-29 and 31-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 10, 18, and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Although a variety of fluids are exemplified in the specification as representative fluids, there is no teaching that any or all of these fluids are of the type to physically entrap an impurity without dissolving the impurity (see pg. 8-9). Thus, the claims present new matter.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan et al. (U.S. Publication 2004/0063663) in view of Inoue et al. (U.S. Patent 5,762,944) and Hughes et al. (U.S. Patent 5,756,659).

Buchanan discloses a method of making a carrier polymer that is used to coat the surface of a stent to provide controlled and sustained release of an anticoagulant drug at the preferred site [0065]. The coating can be formed by putting the carrier polymer along with the other additives into a twin screw extruder [0051]. The polymer can be a thermoplastic material [0059].

Buchanan does not teach 1) introducing a fluid into the extruder, 2) removing at least a volume of the fluid from the extruder such that an impurity is at least partially removed with the fluid, and 3) exposing the fluid to a temperature equal to or greater than the boiling temperature of the fluid at ambient pressure prior to removing the fluid from the mixing apparatus.

Inoue teaches a method of making a coating for a stent, wherein the coating comprises a polymer (col. 3, lines 1-31). Inoue recognizes the need to wash the polymer to remove impurities in the method of making medical devices such as a stent. The impurities can include a solvent, an unreacted monomer, and an impurity (col. 6, lines 38-43). Hughes teaches a method of removing impurities, such as unreacted monomer, solvent, and thermally unstable species, from a molten polymer inside a twin-screw extruder. 1) A stripping agent is introduced into the polymer melt stream and the polymer/stripping agent mixture is homogenized in a mixing zone. 2) At least some of the stripping agent and impurities are removed from the polymer (col. 3, lines 10-33; Fig. 2). 3) The temperature of each extruder zone is controlled by a temperature controller and resistance heaters that are monitored by means of a series of thermocouples 29-36 (col. 3, lines 16-20). The temperatures of the thermocouples range from 112 to 240 °C (Table 6). Such temperatures are greater than the boiling temperature of a solvent, such as those taught in Inoue. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have introduced a fluid into the extruder to have removed impurities from the polymer of Buchanan because Inoue recognizes the need to remove impurities in a method of making a material for a medical device and because Hughes teaches that such an in-situ process is suitable in the art of removing impurities from a polymer. The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945).

Buchanan does not explicitly teach that a solvent and a non-solvent are used as the first and second fluids, respectively, to remove an impurity. However, Inoue teaches that water was a well known fluid to remove impurities from a polymer of an implantable medical device (col. 6, lines 38-43) and Hughes teaches that two fluids can be used to remove impurities (col. 3, lines 23-38). Water is such a common and inexpensive fluid that the use of water as the particular fluid for the two fluids of Hughes would have been an obvious modification. The present specification teaches that water can act as both a solvent and a non-solvent (see paragraph bridging pg. 8-9). The use of water for both fluids can be interpreted as using both a solvent and a non-solvent. Because water is such a common and inexpensive fluid and because Inoue teaches that the use of water was known to remove impurities in the art, it would have been obvious to one of ordinary skill in the art at the time of invention to have used water as the

particular fluid of both of the fluids as taught in Hughes in the method of making stent of Buchanan.

Claims 32-33: Hughes teaches that the extruder temperature ranges from 112 to 240 °C. Such temperatures are greater than the boiling temperatures of the fluids.

5. Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan '663 in view of Inoue '944, and Hughes '659, as applied to claim 31 above, and further in view of Chudzik et al. (U.S. Patent No. 6,156,345).

Buchanan does not explicitly teach that the polymer can be poly(vinylidene fluoride-co-hexaflourorpropene or poly(butyl methacrylate). However, Buchanan does teach that the polymeric material suitable for use in the invention is not limited [0059]. Accordingly, Chudzik teaches that poly(butyl methacrylate) was a well known biostable polymer that can be used for drug delivery devices (col. 1, lines 15-19; col. 5, lines 37-42). Because Buchanan does not limit the choice of the polymeric material and because Chudzik teaches that such polymeric materials were operable for use in drug delivery systems, it would have been obvious to one of ordinary skill in the art at the time of invention to have used poly(butyl methacrylate) as the particular polymeric material of Buchanan with a reasonable expectation of success.

6. Claims 1, 3-5, 8-10, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan '663 in view of Inoue '944, Hughes '659, and Goodson et al. (U.S. Patent No. 4,117,714).

Buchanan discloses a method of making a carrier polymer that is used to coat the surface of a stent to provide controlled and sustained release of an anticoagulant drug at the preferred site [0065]. The coating can be formed by putting the carrier polymer along with the other additives into a twin screw extruder [0051]. The polymer can be a thermoplastic material [0059].

Buchanan does not teach introducing a fluid into the extruder and removing at least a volume of the fluid from the extruder such that an impurity is at least partially removed with the fluid. Inoue teaches a method of making a coating for a stent, wherein the coating comprises a polymer (col. 3, lines 1-31). Inoue recognizes the need to wash the polymer to remove impurities in the method of making medical devices such as a stent. The impurities can include a

solvent, an unreacted monomer, and an impurity (col. 6, lines 38-43). Hughes teaches a method of removing impurities, such as unreacted monomer, solvent, and thermally unstable species, from a molten polymer inside a twin-screw extruder. A stripping agent is introduced into the polymer melt stream and the polymer/stripping agent mixture is homogenized in a mixing zone. At least some of the stripping agent and impurities are removed from the polymer (col. 3, lines 10-33; Fig. 2). 3) The temperature of each extruder zone is controlled by a temperature controller and resistance heaters that are monitored by means of a series of thermocouples 29-36 (col. 3, lines 16-20). The temperatures of the thermocouples range from 112 to 240 °C (Table 6). It would have been obvious to one of ordinary skill in the art at the time of invention to have introduced a fluid into the extruder to have removed impurities from the polymer of Buchanan because Inoue recognizes the need to remove impurities in a method of making a material for a medical device and because Hughes teaches that such an in-situ process is suitable in the art of removing impurities from a polymer. The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945).

Buchanan, Inoue, and Hughes do not explicitly teach that the fluid is a type to physically entrap the impurity without dissolving the impurity. However, Goodson teaches that there are only a finite number of identified, predictable potential solutions in the method of removing impurities. Specifically, Goodson teaches that an impurity can be removed from a medium by either dissolving or entrapping the impurity in a fluid (col. 3, lines 39-42). One of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success (see MPEP 2145.X.B.). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have used a fluid to physically entrap the impurity, as opposed to a fluid to dissolve the impurity, in the method removing the impurity of Buchanan with a reasonable expectation of success and with predictable results.

Claim 3: Buchanan teaches that a single screw extruder can also be used [0051].

Claim 4-5: Buchanan teaches that the polymer must be melted in the extruder [0051].

Claim 8: Hughes teaches that a second stripping agent can be introduced to the extruder, wherein the stripping agent removes an impurity from the polymer (col. 3, lines 33-45).

Claim 9: Buchanan teaches that a suitable thermoplastic can be polyethylene-vinyl acetate copolymer (i.e., an ethylene-vinyl acetate copolymer) [0059].

Claim 10: Inoue teaches that a suitable fluid can be water (col. 6, lines 38-43).

Claim 35: Hughes teaches that the fluid is exposed to temperatures ranging from 112 °C to 240 °C (Table 6).

7. Claims 13, 16-18, and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan '663, Inoue '944, Hughes '659, and Goodson '714, as applied to claim 1 above, and further in view of Berg et al. (EP 0623354).

Buchanan, Inoue, and Hughes are discussed above, but do not explicitly teach that the polymer can be combined with a solvent. However, Berg teaches that a solution comprising a polymer and solvent can be applied to the coating of a stent and then evaporating the solvent (abstract). The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have applied the polymer of Buchanan, Inoue, and Hughes in a solvent solution and then evaporating the solvent because Berg teaches that such a coating method is suitable in the art of coating a stent.

Claim 36: Buchanan, Inoue, and Hughes do not explicitly teach introducing a second fluid that is of a type that dissolves the impurity. However, Hughes does teach that a second fluid is introduced to remove impurities and Goodson teaches that there are only a limited, potential solutions for removing impurities from a medium. One of ordinary skill in the art would have recognized that the use of a fluid having the properties either to entrap or to dissolve an impurity as the particular second fluid would have been operable and that the use of one over the other would have yielded predictable results. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have used a fluid that is of a type that dissolves an impurity, as opposed to one that entraps an impurity, as the particular second fluid of Hughes with a reasonable expectation of success.

Claims 16-18 and 37 are rejected for substantially the same reasons as claims 4-5, 9-10, and 35 above.

8. Claims 23-27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan '663 in view of Inoue '944, Hughes '659, and Goodson '714, as applied to claim 1, and further in view of Anders et al. (U.S. Patent No. 6,096,369).

Buchanan, Inoue, Hughes, and Goodson are discussed above, but do not explicitly teach that the fluid is selected from FLUX REMOVER AMS, dimethyl acetamide, dimethyl formamide, cyclohexane, dimethyl sulfoxide, and combinations thereof. However, Anders teaches that it was well known to use cyclohexane to remove residual monomers from a polymeric material in the field of implantable medical devices (col. 9, line 58-col. 10, line 4). Because Anders teaches that such a fluid was operable in the art for removing monomers, it would have been obvious to one of ordinary skill in the art at the time of invention to have used cyclohexane as the particular fluid to remove the residual monomers of Buchanan with a reasonable expectation of success.

Response to Arguments

9. Applicant's arguments, see pg. 4, filed 4/14/2008, with respect to the rejection(s) of claim(s) 34 under 35 U.S.C. 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Buchanan, Inoue, Hughes, and Chudzik.

10. Applicant's arguments, see pg. 6-7, filed 4/14/2008, with respect to the rejection(s) of claim(s) 23-27 and 29 under 35 U.S.C. 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Buchanan, Inoue, Hughes, Goodson, and Anders.

11. Applicant's arguments filed 4/14/2008 have been fully considered but they are not persuasive.

Rejections under 35 U.S.C. 112

Applicant argues on pg. 2 that Applicant has demonstrated that at least one of the fluids, water in particular, listed in claims 10, 18, and 28 is of the type to physically entrap an impurity

without dissolving the impurity. However, water as a fluid is only one of many of the fluids listed in the claims. Applicant has not shown possession of the other fluids being of the type to physically entrap an impurity without dissolving the impurity.

Rejections under 35 U.S.C. 103

Applicant argues on pg. 3 that dissolving the impurity and entrapping the impurity without dissolving the impurity are two approaches Applicant has identified for removing impurities from a polymer and that none of the cited references recognize a distinction between using solvents and non-solvents or suggest the desirability of using a combination of a solvent and a non-solvent to remove impurities from a polymer. However, the present specification teaches that water can act as both a solvent a non-solvent (see paragraph bridging pg. 8-9). Inoue teaches that water was a well known fluid to remove impurities from a polymer of an implantable medical device (col. 6, lines 38-43) and Hughes teaches that two fluids can be used to remove impurities (col. 3, lines 23-38). Water is such a common and inexpensive fluid that the use of water as the particular fluid for the two fluids of Hughes would have been an obvious modification. Because water can be both a solvent and a non-solvent, the use of water for both fluids can be interpreted as using both a solvent and a non-solvent.

Applicant argues on pg. 4-5 that Goodson teaches "the air 18 is scrubbed as it passes through and above the rotating film 20 and any impurities therein are dissolved or entrapped in the water film" and that this statement at most teaches that impurities may be removed from air by passing them through a film of water. However, Goodson teaches that a fluid can remove impurities either by dissolving or entrapping the impurities. Goodson suggests that there are only a limited number of solutions for removing impurities. One of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success.

Applicant argues on pg. 5 that Examiner has not provided support or explanation as to why an organic solvent or water of Inoue must necessarily (1) physically entrap monomers and (2) would not dissolve the monomers. However, Inoue teaches that other fluids can be used to remove impurities. As to the selection of the fluid, one of ordinary skill would have selected a suitable fluid having either a dissolving or an entrapping property because Goodson teaches

limited potential solutions for how impurities are removed, and pursuing the limited number of known solutions would have been obvious.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Iguchi et al. (U.S. Patent 5,756,553) recognizes the need to remove impurities from polymers used for medical devices (col. 4, line 66 – col. 5, line 2).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jimmy Lin whose telephone number is (571)272-8902. The examiner can normally be reached on Monday thru Friday 8AM - 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tim Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jimmy Lin/
Examiner, Art Unit 1792

/Timothy H Meeks/
Supervisory Patent Examiner, Art Unit 1792